# Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION®)

## Public-Private Partnership

# GOVERNANCE STRUCTURE and BY-LAWS

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Conflict of Interest policy added February 24, 2023

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# 1. INTRODUCTION

Beginning in 2010, the United States Food and Drug Administration (FDA) awarded two contracts and four cooperative agreements to the University of Rochester School of Medicine and Dentistry to support the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership. ACTTION was established to address public health needs for improved treatments for pain, anesthesia, and addiction with greater efficacy and safety by optimizing the research methods used for evaluating innovative preventive, disease-modifying, and symptomatic interventions. The key objectives of ACTTION involve initiating and supporting strategic collaborations among a broad spectrum of stakeholders — including academia, national and international government agencies, industry, professional organizations, patient advocacy groups, foundations, and philanthropic organizations — with the goals of sharing data and state-of-the-art considerations and challenges. These strategic collaborations involve a wide range of activities, for example, systematic reviews and meta-analyses, evidence-based consensus meetings, and various preclinical and clinical research projects.

ACTTION is a not-for-profit unincorporated association formed to advance the mission and objectives set forth in this document. This document presents the ACTTION Governance Structure and By-laws, and describes the framework for how ACTTION (1) is organized and governed; (2) includes stakeholders from professional societies, academia, industry, patient advocacy organizations, and government agencies; and (3) generates and maintains intellectual property and financial resources to achieve its mission and objectives. ACTTION's current sources of support include an FDA cooperative agreement grant that expanded ACTTION's activities to address FDA's Pediatric Anesthesia Safety Initiative (PASI), as well as funds from industry, philanthropy, and royalties.

# 2. MISSION STATEMENT

The mission of the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership with the U.S. Food and Drug Administration (FDA) is to identify, prioritize, coordinate, and sponsor innovative activities that will expedite the identification and development of efficacious and safe analgesic, anesthetic, and addiction therapeutic interventions for the benefit of the public health.

# 3. ORGANIZATION

ACTTION is an independent unincorporated voluntary association of participants from diverse national and international public and private organizations -- including professional societies, academia, industry, patient advocacy organizations, and government agencies -- who are committed to the development of safe and effective pain, anesthesia, and addiction treatments for improving the public health.

The policies and procedures for public-private partnerships and consortia of the FDA Center for Drug Evaluation and Research should be consulted for a description of the roles and responsibilities of FDA employees interacting with outside organizations such as ACTTION (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM532571.pdf).

# 4. HEADQUARTERS

The ACTTION Headquarters is maintained at the University of Rochester School of Medicine and Dentistry. The Headquarters comprises the Management Committee (MC) and is where all revenues, expenses and other disbursements, and finances are maintained, transacted, recorded, monitored, and audited in specifically designated accounts as authorized by the MC and verified by a designated individual from the University of Rochester assigned to ACTTION. If the ACTTION Headquarters is not able to support any specific activities (e.g., data management and analysis), such activities can be conducted at other venues with oversight provided by the MC.

At the time of approval of this document, budgetary support for ACTTION is provided by the Sponsored Research Center of the Department of Pharmacology and Physiology and by the Department of Anesthesiology and Perioperative Medicine at the University of Rochester School of Medicine and Dentistry. Administrative and logistical support for meetings and related activities are provided by Valorie Thompson, RN, President of Innovations Consulting Group.

To keep all ACTTION participants and the public informed of its progress, a website is maintained (www.acttion.org). The ACTTION Director and Co-Director, with the support of the MC, oversee the content and regular updating of this website. The website presents ACTTION's mission; organizational structure; meetings; news; publications; various clinical trial databases and other resources; a link to the website of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), which was subsumed within ACTTION in 2011; sources of financial support; and lists of professional societies and other organizations that are affiliated with ACTTION's consortia, center, and working groups

# 5. GOVERNANCE STRUCTURE

## 5.1. Management Committee (MC)

The MC currently consists of:

- Robert H. Dworkin, PhD, Director and Chair
- Dennis C. Turk, PhD, Co-Director and Co-Chair
- Robert R. Edwards, PhD, Director of Translational Science

- Dale J. Langford, PhD, Director of the Center on Patient and Stakeholder Engagement for Trial Innovation and Quality (COPASETIQ)
- Michael P. McDermott, PhD, Director of Biostatistics
- Bryce B. Reeve, PhD, Director of Clinimetrics
- Denham S. Ward, MD, PhD, Director of Stakeholder Engagement

These individuals oversee and implement the activities of ACTTION, as follows:

- Development of procedures for the identification, prioritization, and implementation of administrative activities.
- Overall management of administrative coordination for all ACTTION activities.
- Specific project management activities as reviewed and approved by the MC.
- Serving as the intellectual property and fiscal representative for ACTTION and conducting reporting functions and authorizing accounts payable.
- Providing support for scientific workshops and evidence-based consensus meetings, including preparation of meeting announcements and invitations, development of meeting agendas, transcripts and draft manuscripts, and coordination of travel, hotel, meals, and audio-visual support.

The MC has overall management and financial oversight for ACTTION's intellectual and financial resources. This role is retained by the MC independent of any financial or other support received by ACTTION, including but not limited to support from industry, foundations, and grants and contracts from government agencies, including FDA.

The MC will require that all participants associated with ACTTION and its activities are in compliance with Federal regulations to the extent required and also with any applicable conflict of interest policies of their own institutions and any institutions in which they conduct ACTTION research studies or other activities. In addition, all individuals associated with ACTTION must adhere to the Conflict of Interest policy contained in Section 6.

Meetings of the MC will typically occur quarterly and on an as-needed basis. Minutes will be prepared and distributed to all committee members in advance of the next meeting, during which the minutes will be reviewed, revised if necessary, and then approved. If the Director of ACTTION is unable to chair an MC meeting, the Co-Director will chair the meeting.

If there is a vacancy on the MC, the remaining members of the MC may elect a new member to serve on the committee. If the Director of ACTTION becomes unable to serve in that capacity, the Co-Director will automatically become the new Director. In the event that both the Director and the Co-Director cannot serve in those capacities, the other members of the MC will convene and appoint a new ACTTION Director and Co-Director.

## 5.2. ACTTION/PASI Executive and Steering Committees

The four consortia included within the current FDA cooperative agreement will be overseen by an ACTTION/PASI Executive Committee and will each have separate Steering Committees. These consortia are the Consortium on Pain Efficacy, Effectiveness, and Safety Studies (COPESS), the Consortium for Addiction Research on Efficacy and Safety (CARES), the Consortium on Anesthetic Agents and Modulators (CAAM), and the Consortium on Maximizing Pediatric Anesthesia Safety (COMPAS). The ACTTION/PASI Executive Committee will be responsible for reviewing the progress of these four consortia and other grant-related activities, such as preparing for yearly progress reports. In addition to the ACTTION Director and Co-Director, the Executive Committee will include the consortium Chairs and Co-Chairs as well as Cornelia Kamp, MBA, who will serve as Director of Operations, Christin Veasley, BA, who will serve as Director of Patient Engagement, and representatives of FDA's Division of Anesthesiology, Addiction Medicine, and Pain Medicine.

The members of the ACTTION-PASI consortium Steering Committees will be drawn from professional societies, patient advocacy groups, academia, industry, and others with experience or expertise relevant to the preclinical and clinical discovery and development of treatment interventions with improved efficacy, effectiveness, and safety. Efforts will be devoted to ensuring that the membership of these ACTTION-PASI Steering Committees is diverse and broadly representative of individuals with different backgrounds and at different stages of their career.

## 5.3. Other Committees

The organizational structure of ACTTION includes Advisory Committees and Working Groups that are typically associated with a consortium or center. In addition, a Scientific Review Panel will evaluate ACTTION's overall progress and provide strategic support in fulfilling ACTTION's scientific mission, specifically by providing advice and guidance to the MC. On an annual or more frequent basis, the Scientific Review Panel will conduct systematic evaluations and will assist in identifying and prioritizing additional research studies and other activities.

## 5.4. Participation in ACTTION Activities

Participants in ACTTION will include individuals representing the major stakeholders involved in relevant research and other activities, including academia; professional societies; interested regulatory and other government agencies; patient advocacy groups; the pharmaceutical, biologics, and device industries; and trade, contract research, and laboratory organizations. These participants will include national and international entities, and ACTTION will strive to ensure that its consortia and committees include diverse participants representing different career stages and professional specialties.

ACTTION will seek broad and diverse involvement in its activities through the contributions of its participants in accomplishing its mission. Industry involvement will

typically be dependent on the provision of financial support for ACTTION and its activities. All participants and participating organizations are expected to make meaningful contributions to ACTTION's specific activities and projects, including but not limited to, data, expertise, infrastructure, funding, and other resources. Failure to meaningfully contribute to ACTTION's activities may result in termination of membership in the relevant consortium, steering or advisory committee, or working group.

Because of the broad scope of ACTTION, it is imperative that multiple health disciplines are involved in the development of improved research methods and ultimately treatments with greater efficacy and safety. To address this goal, the ACTTION consortia and centers will seek to include a broad range of professional, government, and patient advocacy organizations. Each participant will be responsible for representing the views of their organization and informing that organization of ACTTION initiatives and accomplishments. They will generally be appointed by their organization and may serve for an unlimited amount of time or may be replaced at the discretion of the organization they represent. Professional societies and other organizations may apply for a role in ACTTION by submitting a written request to the Director of ACTTION, who will review the structure and mission of the requesting professional organization and will determine, in consultation with Chair and Co-Chair of the relevant ACTTION group, whether that organization should be invited to appoint a participant.

## 6. CONFLICT of INTEREST

The ACTTION MC and the ACTTION-PASI Executive Committee will require that all individuals associated with ACTTION adhere to Federal regulations. This includes any FDA specific policies and procedures (to the extent required) and any applicable conflict of interest policies and requirements of their own institutions and of any institutions or organizations in which they conduct ACTTION research studies or other activities. In addition, all individuals associated with ACTTION activities will be required to provide an annual conflict of interest disclosure during each year's first quarter for the calendar year preceding the disclosure that describes industry and other financial relationships. Each source of financial remuneration that could potentially be a conflict of interest related to their ACTTION responsibilities or their participation in ACTTION activities must be disclosed, including but not limited to cash payments, equity, stock options, royalties, and patents. In addition, an attestation indicating whether or not the respondent believes that he or she has such a conflict of interest that must be discussed and resolved by the ACTTION MC and ACTTION-PASI Executive Committee must be included with the annual disclosure. Any potential conflict of interest that occurs between the annual disclosures that is related to ACTTION responsibilities or participation should also be disclosed at the time it occurs.

The ACTTION MC and the ACTTION-PASI Executive Committee will carefully review all of the disclosures provided within 15 working days of their submission and

seek to resolve potential conflicts of interest. Depending on the specific circumstances, conflicts can be resolved in different ways, including recusal from specific ACTTION activities, change in the person's responsibilities associated with one or more ACTTION activities, cessation of the consulting or other relationship that causes the conflict, or removal from any and all ACTTION activities.

This policy is available on the ACTTION website in this Governance Structure and By-Laws document, and the website will also include all of the annual disclosures for the previous calendar year. ACTTION also requires that disclosures of potential conflicts of interest be included on all of its publications when the specific journal's policies do not already require such disclosure. In addition, all presentations at ACTTION meetings, whether virtual or in-person, must include a disclosure slide for the presenter at the beginning of the presentation that includes all industry and other financial relationships that present a potential conflict of interest or appearance of conflict of interest that could impact the presentation in any way.

## 7. FUNDING

ACTTION will pursue funding from a variety of sources, including government grants and contracts (e.g., FDA, NIH, PCORI), support from industry, philanthropic contributions, royalties, and other miscellaneous revenue.

ACTTION funds that originate from grants and contracts from government agencies are subject to standard Facilities and Administrative (F & A) costs. ACTTION funds that do not originate from government sources (e.g., support from industry or philanthropy) are not subject to F & A costs. F & A costs are not levied on such funds nor are they paid to outside universities, organizations, agencies, or other groups. A quarterly budget review conducted by the MC authorizes all payments by the ACTTION Headquarters from these ACTTION non-government funds. At the University of Rochester, these ACTTION funds are held by the University as a custodian of the funds.

At the time of approval of this document, ACTTION maintained funds in the University of Rochester custodial account that had accumulated since it was established in 2010. These funds were specifically provided to ACTTION to support its activities related to analgesia and addiction. In reviewing and approving the use of these funds, the MC will adhere to ACTTION's fiduciary responsibility to generally limit use of these funds to these two therapeutic areas.

## 8. ANTI-TRUST GUIDELINES

ACTTION will handle all anti-trust issues in compliance with federal standards (Sherman Act 15 U.S.C sect 1 *et seq)*. Specifically, any indication of improper commercial bias or facilitation of collusion (directly or indirectly) associated with the legitimate scope of ACTTION activities could expose its members and other

participants to anti-trust risk. Issues may arise that could have anti-trust implications, which include but are not limited to:

- Use of ACTTION unfairly to promote a particular technology or product or exclude another for commercial reasons; and
- Inappropriate sharing of confidential or competitively sensitive information of competing companies, including intellectual property, pricing, production, or innovative plans.

All participants in ACTTION and its activities will need to abide by guidelines based upon federal standards to prevent such risk, as follows:

- Private partners may freely conduct activities that do not infringe on intellectual property of other members and participants or intellectual property generated by ACTTION.
- No member shall take or seek action relating to ACTTION for purposes of excluding products or technology of competitors from the market or impeding research and development.
- The Director and Co-Director, with input from the MC as needed, must review and approve all public communications and data sharing activities.

## 8.1. Restricted Topics

The following is a list of restricted topics that should not be shared or discussed during any meetings, teleconferences, or events conducted under the auspices of ACTTION:

- Pricing, pricing policies, market shares, services of private partners.
- Intentions about commercial activities, including advertising, promotion, research and development outside ACTTION, or whether to deal with specific customers (including government programs).
- Speculation or prediction about commercial activities of private and publically traded partners in response to business or legislative developments.
- Discussion of any topic of commercial significance to competitors that may involve anti-trust compliance.

# 9. INTELLECTUAL PROPERTY GUIDELINES

Any attempt to establish broad rules for intellectual property protection for a voluntary association such as ACTTION are necessarily limited by the somewhat open-ended nature of the research projects and other activities that will be conducted. As a result, the following ACTTION policy on intellectual property has been designed to establish general principles that are likely to apply to most of the anticipated activities but that also allows for flexibility depending on specific circumstances.

- Intellectual property or work products arising out of ACTTION will typically be made freely available and not subject to proprietary intellectual property protection.

- Exceptions can be made to this general rule for specific work products that involve substantial resource investment by ACTTION or one or more ACTTION collaborators or grantees that justify the intellectual property protection of the work product. Such exceptions would be subject to approval by the MC.

## 10. DATA SHARING GUIDELINES

Sharing data from public and private partners is anticipated to expedite the work of ACTTION. Confidential scientific data may be shared by ACTTION participants, subject to intellectual property, anti-trust, data sharing, and FDA confidentiality policies and other federal laws. Participants should not share data or other confidential information about commercial activities with each other, particularly restricted topics (see Section 7). The MC and legal counsel of the participants should be consulted on the appropriateness of:

- Data sharing; note that FDA must approve all access to and analyses of sponsor data received from FDA as a result of the award of contracts.
- Confidential and commercial information.
- Subject to foregoing precautions, if unaggregated, confidential, and competitively sensitive information or data are collected by the ACTTION public-private partnership, such information should never be shared outside the project team.
- Any data collected from private participants should include statements that the information will be handled in conformity with ACTTION guidelines.
- Any personal information from participants in ACTTION-sponsored research will meet all applicable HIPAA standards.

## 11. PUBLICATIONS and PUBLICITY

The ACTTION Publications Policy is designed to promote the scientific and technical accuracy, integrity, and dissemination of all ACTTION publications and ensure that appropriate credit is given to the authors and to other individuals who have contributed to the ACTTION scientific efforts. ACTTION participants are encouraged to conduct high-quality research and other scientific efforts and to publish their results in peer-reviewed journals and other appropriate outlets in a timely manner. By agreeing in advance how publication issues will be handled, potential disagreements among ACTTION participants will be minimized. This section presents ACTTION's overall publication policy, which provides for some flexibility. By way of definition, a publication is any document submitted to a peer-reviewed journal, scholarly text, popular periodical, or any other media.

Publication of ACTTION data and other activities undertaken without conforming to these policies is not permitted without prior written consent from the ACTTION Director and Co-Director, with input from the MC as needed. None of the rules contained herein should be allowed to contravene the principles that all individuals

who have made substantial intellectual, scientific, and practical contributions to the work described in the manuscript should, when they agree, be credited as authors. All individuals credited as authors should deserve that designation, and the following guidelines should be followed.

- All manuscripts resulting from ACTTION's activities or support should be published in peer-review journals and appropriate credit should be given to ACTTION.
- The ACTTION publication policy generally adheres to the authorship policies set out in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (International Committee of Medical Journal Editors).
- ACTTION requires that all authors review any data analyses and interpretation, and always carefully review and provide approval for publication of the manuscript.
- Failure to provide timely input and feedback during the preparation and approval of manuscripts being submitted for publication may result in termination of authorship.
- The status of manuscripts in preparation will be reviewed at each ACTTION MC meeting as a standing agenda item.
- Final versions of all journal manuscripts should be submitted to PubMed Central as soon as possible upon acceptance for publication.

Acknowledgements of specific contributions by individuals who do not qualify for authorship should be made for one or more of the following: administrative, technical, and materials support; and other contributions. In addition, all articles should acknowledge all support from any organizations providing financial support or other resources, such as data or clinical trial materials, as well as ACTTION.

The MC will promote, facilitate, and monitor the timeliness of all ACTTION publications. The MC and relevant consortium or center steering committees will review, provide comments on, and approve all publications prior to submission, enlisting the special assistance of other ACTTION participants whenever appropriate. Reviews will be conducted pursuant to the following general editorial responsibilities: (1) ensure that all ACTTION publications preserve the scientific and scholarly integrity of the work; (2) correct factual and conceptual inaccuracies, if necessary; (3) safeguard the rights and confidentiality of volunteer participants; (4) prepare comments to assist collaborating scientists in publishing papers of the highest quality and clarity; (5) avoid conflict with and/or duplication of other publications; and (6) ensure that ACTTION is appropriately acknowledged in the publication. In addition, the MC will maintain an up-to-date bibliography and repository of all publications pertaining to ACTTION activities. The complete ACTTION bibliography will be maintained on the ACTTION website.

## 11.1. Publicity, Press Releases, and Interviews

ACTTION defines a press release as a document provided to media (e.g., radio, television, newspapers, popular periodicals, social media), scientific journals, or

scholarly texts. An interview is any discussion with a member of the press, a science writer, or a radio, television, or social media/blog commentator, which in turn provides information for public dissemination. Press releases and interviews should not be initiated by individual ACTTION participants without prior authorization from the ACTTION Director and Co-Director. All press releases must be reviewed and approved by the ACTTION Director and Co-Director and FDA (if named within the press release) and any other named entities (e.g., pharmaceutical companies and other industry and non-industry sponsors) prior to release. Should a participating ACTTION participant be solicited for information other than as that detailed above, the individual and/or organization should refer the soliciting party to the ACTTION Director and Co-Director.

## 12. AMENDMENTS and DISSOLUTION OF ACTTION

Should the FDA requirement for, or interest in, continuing a public-private partnership with ACTTION change, ACTTION will use its good faith efforts to amend its Governance Structure and By-laws to conform to any new FDA requirement. Should the FDA wish to terminate its public-private partnership with ACTTION, ACTTION will continue as an unincorporated association supported by non-governmental funding it has and will receive to support its efforts.

Amendments to the Governance Structure and By-laws of ACTTION may be proposed by any member of the MC and must be made in writing and submitted to the Director of ACTTION. The Director will ensure that the proposed amendment is distributed to the entire MC and the proposed amendment will be considered and voted upon by the committee in person or electronically. Amendments must be approved by an affirmative vote by written ballot of a two-thirds majority of all members of the MC.

Dissolution of the ACTTION public-private partnership will be decided by an affirmative vote by written ballot of a two-thirds majority of all members of the MC.